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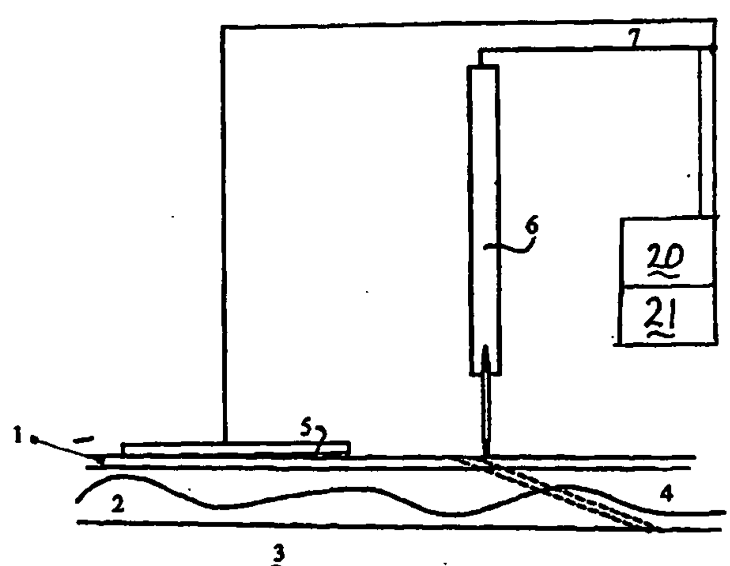

(57) Abstract

A skin impedance imaging system is disclosed which comprises a probe (6) having an electrode which is intended for movement over a patient's skin. A reference electrode (5) is applied to the patient's skin and an alternating current is supplied to the probe (6) and/or reference electrode (5) so the current flows through the patient's skin. An alternating current supply (20) and a device for measuring voltage changes (21) are provided so that a measure of the impedance of the skin can be obtained, thereby providing an indication of the induced or pathological changes in the skin. An image of the impedance changes across various areas of the skin can be produced.

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SKIN IMPEDANCE IMAGING SYSTEM

Background

The skin of a living creature conducts electricity differently depending on the frequency and voltage that is applied. This property is referred to as electrical impedance (complex skin impedance). Changes in the skin at different levels effect the resistance to an applied electrical voltage differently. Changes in conductivity at the very surface of the skin effect its resistance to a direct current (DC) applied across the skin. The resistance of the skin to a DC voltage is generally very high in the order of 10 megaohm but certain changes, for example, thinning of the outer dry layer (epidermis) decreases this significantly as do changes in the oil content of the outer layer.

By contrast, very high frequency alternating currents, above one megahertz for example, are not always greatly effected by the changes in the upper layers of the skin. Many frequencies pass through the skin and are effected more by the volume of tissue they pass through below. Therefore different frequencies may identify changes at different depths through the skin.

The skin is itself not a simple structure microscopically or electrically. It is made up of two major layers; the outer epidermis and the inner dermis. The dermis contains the vessels, nerves, immune cells and supportive structural

collagen. Its appearance under the microscope varies to some extent from one part of the body to another both in thickness and composition. The upper layer of the dermis is a single layer of cells from which comes the scaly layer that make up the epidermis. These scales form as tightly connected cells which dry out and thin as they migrate to the surface where they eventually slough or flake off.

Changes in the blood flow in the dermis, changes in the water content of the dermis, changes in acidity and even changes in the cell populations in the dermis may alter the resistance to electricity differently. The thickness of the epidermis and its water content will have an effect.

One other compounding factor is that electricity follows the path of least resistance, therefore it should be noted that, increasing the surface area of the contacting electrode changes the measured resistance. However, once through the skin, electricity behaves as it would passing through a bag filled with salty water.

Description of the invention

It was discovered that this property of the differing changes in the skin causing different changes to the electrical impedance of the skin could be used to determine local pathology within the skin. A great deal is known about the effect of skin on the normal use and function of skin applied electrodes. The localised pathological effects are not known. Even though greatly different pathological changes may cause identical changes in electrical impedance at some frequency, the ability to distinguish between

normal and abnormal skin, producing a contrast, would allow the formation of an image or demarcation line. This has tremendous benefit to medical practice.

Even if specific pathology can not be identified, for example, cancerous growths of different types may produce the same electrical change, the system still provides tremendous advantage by separating healthy from abnormal. Two particular examples are the determination of depth of a burn and the identification of localised pathology such as in situ skin tumours and immune response to an injected antigen.

Burns penetrate to differing degrees through the epidermis and dermis. If only the epidermis is destroyed, then the burn is minor and will heal without scar. If the dermis is completely destroyed then the burn will not heal without tremendous scar formation and the dead skin will have to be removed and tissue grafted into place. In between these two extremes are varying degrees of healing that may or may not require any surgical intervention. The problem which has afflicted burn surgery, even to the present day, is that there is no reliable way to determine the depth in these transition areas. The surgeon must wait, often for a week, until the body itself declares the region that needs to be removed. This is done either by identifying a line of healing at the edge where the body is trying to remove the dead tissue or, by a pattern of bleeding which is visible when the surgeon cuts through the skin tangentially.

The problem with the delay is that during this period the "burns patient" suffers severe fluid and metabolic disturbances and is at risk of fatal sepsis. In children

this is particularly difficult to manage and is often the cause of death days after the burn. If it were possible to identify the area to be excised then this period could be avoided. Even if there is no serious consequence in the short term, the release of tissue factors by the dead and dying tissue induces scar formation which is often disfiguring and the worst consequence of the burn itself.

The present invention provides a method for measuring or imaging induced or pathological changes in the skin using electrical impedance, said method including:

applying an alternating electrical current to the skin through an electrode or multiple electrodes;

measuring the change to the applied electrical current produced by the relative impedance of the underlying skin; and

producing a representation of the relative measurement for differing areas of skin.

The present invention also provides an apparatus for measuring or imaging induced or pathological changes in skin, said apparatus including:

a measurement electrode for movement across the skin;

at least one reference electrode for application to the skin;

means for providing an alternating electrical current, coupled to the measurement electrode and/or reference electrode for supplying the current to the measurement electrode and/or reference electrode; and

means for providing a measure of the change in the alternating current indicative of the change in impedance of the skin as the measurement electrode is moved

over the skin to provide an indication of the induced or pathological changes in the skin.

Using a pen-like probe and frequencies in the range of, for example, 2 to 100 kHz, the difference between live and dead tissue and the damaged tissue in between can be mapped electrically. This can be used to produce a graphical image on the screen or a to draw changes on the skin using a printing system to identify the depth of the burn for the surgeon.

The probe needs to be grounded. Using a larger surface area probe tends to decrease the influence of the skin under that electrode. Therefore, changes in the moving electrode or, alternatively, in an array of pin point electrodes can be used to map an area of interest.

Another example is the demarcation of an intradermal cancer. Many cancers, such as melanoma, spread imperceptibly through the skin invisible from above. No such spreading occurs with benign skin lesions. Graphing the skin with an array or moving probe may identify deep changes in the dermis which would otherwise only be visible on an excised and specifically stained section.

When a tuberculosis test is performed, the skin is injected with an antigen and the immune cells of the body are attracted and form a swelling. If the reaction is large, then the physician knows that the individual has been exposed to TB. Unfortunately, the test is often badly performed because there is no objective way to determine the volume of the reaction. Instead, a practitioner tries

to feel the area of thickening in the skin produced by the reaction and then measure this in millimetres.

The method described here can be used to map changes in impedance and therefore indicate areas of pathology such as damage due to burn, invasion by cancerous cells of the accumulation of an immune response. The essence of the device is not to measure in absolute impedance measurement as the skin's impedance can vary markedly from individual to individual, in different areas of the body and overtime, but to compare and indicate significant local differences in impedance compared to the normal surrounding skin.

In the following, the invention will be explained, by way of example, with reference to the drawings, wherein:

Figure 1 schematically shows the skin and the applied single point electrode; and

Figure 2 schematically shows the skin and the applied multiple electrode apparatus.

Skin thickness varies in different parts of the body but within certain limits. Typically, in an adult, it is a little less than 1 mm thick. A single point electrode can be placed in different parts of the body to give relative measures of the absolute skin impedance. An alternating current is placed across two electrodes separated by some distance, usually several centimetres, and the resistance to the applied voltage can be measured. The measurement can be made by measuring the voltage directly across the two electrodes themselves or between one of the two source electrodes and a third electrode placed on the skin.

Figure 1 illustrates one preferred embodiment. The layers of skin are the epidermis 1 and the dermis 2. The tissue below the skin is referred to as the subcutaneous layer 3. One important feature of the subcutaneous layer is that it is essentially one large relatively homogeneous volume. Once a current passes through the skin at one point, it can pass through innumerable pathways to any part of the skin on the body. This is important to the principle employed in this invention. In this invention, the absolute impedance is of less importance than the relative impedance of one area of skin compared to its neighbour. In Figure 1, the area of damaged tissue 4 will be measured relative to the normal skin 1 and 2, as the probe 6 is moved over it.

The reference electrode 5 represents a large surface area electrode. In one configuration there may be two such electrodes (second not shown) and the source voltage is applied to them. The measurement is made between one of the two electrodes and the sensing probe 6. In Figure 1, only one electrode is visible and this configuration can be used directly with certain signal generating circuits. In both configurations, the electrodes are connected by wires 7 to some means of generating an alternating current 20 or oscillating signal and a means to measure the voltage changes 21. The means for generating the signal and measuring the voltage are many and varied and not specific to the method.

The larger surface area electrode permits the signal to penetrate the skin through a lower resistance than at the measuring point. To the measuring probe itself it is as if the electrode were below the skin and the current passes directly through the skin more or less at right angles to

the surface. In reality, the reference electrode and detecting electrode have to be within millimetres of each other for much of the current to pass along the skin between them rather than through the skin, then through the body and then out through the skin at some distant point.

When direct current is used most of the resistance is produced at the contact boundary layer. The resistance can be seen to increase over time and this is due to the build up of charge so called galvanic resistance. This does not occur with alternating current. The voltages typically used are in the range of a few volts and are not only of little consequence they are generally imperceptible. The higher the frequency the higher the voltage that can be applied without detrimental effect.

The sensing probe can have differing materials and geometry for different application but is typically a copper wire of 0.5 mm diameter. Silver, gold and carbon are excellent materials and the diameter can be finer for higher resolution. There is a practical limit to the resolution imposed by the skin's thickness itself. The thinner the skin the higher the resolution that might be achieved.

Figure 2 illustrates a second preferred embodiment wherein, instead of a single electrode which is moved across the skin, multiple stationary electrodes 9 are employed. The electrodes 9 are built into a insulated block with a flat end surface 10 with only the ends exposed to make contact with the skin. The electrodes 9 may be built into a three-dimensional array or grid pattern to produce an electrical image of the area covered by them or alternatively into a linear array for measuring across a boundary layer. In the

configuration shown, two large surface area electrodes 8 are attached to the block and placed near the electrodes. One of the two electrodes 8 can then be used as the reference electrode for measurements on each individual element of the electrode array 9. As discussed previously, the electrodes could be placed elsewhere on the body. As with the previous configuration the electrodes are connected by wires 11 to both a means for generating the alternating current signal and means for measuring the impedance. Many arrangements for measurement of the impedance are possible and are not specific to the method. The probe would be placed over normal skin to produce a reference image and then over an area of suspected pathology to produce an image. Because the geometry of the electrodes are known, the method lends itself easily to measuring the area or distance across a pathological lesion as a tumour or intradermal inflammatory mass.

The impedance measurements obtained by this method could be used to produce an image on a screen or printed page or conversely used to guide a printing process directly applied to the skin to permit a surgeon or physician to know the size and location of the pathological lesion. The relative measure is all that is necessary to produce the image and the information of most value may come from the area or location on the image produced. With finer resolution and sensitivity to the relative changes in impedance such as whether it is increased or decreased may be used to better identify the pathological change. It may be possible thereby to separate inflammation from cancerous growth or foreign body from infection.

Preferred embodiments of the invention may also utilise a mechanism for determining the position of the electrode 6 in three-dimensional space so that as the electrode 6 moves over the surface of the skin the contour of the skin in three-dimensional space can be measured by the moving electrode. This enables an indication of the skin topography to be provided as well as measurements of the impedance of the skin and therefore the induced or pathological changes in the skin which are desired to be measured.

The described arrangement has been advanced by explanation and many modifications may be made without departing from the spirit and scope of the invention which includes every novel feature and novel combination of features hereindisclosed.

Those skilled in the art will appreciate that the invention described herein is susceptible to variations and modifications other than those specifically described. It is understood that the invention includes all such variations and modifications which fall within the spirit and scope.

CLAIMS:

1. A method for measuring or imaging induced or pathological changes in the skin using electrical impedance, said method including:

applying an alternating electrical current to the skin through an electrode or multiple electrodes;

measuring the change to the applied electrical current produced by the relative impedance of the underlying skin; and

producing a representation of the relative measurement for differing areas of skin.

2. A method as in claim 1 wherein the applied electrical current is in the frequency range from 100 Hz to 1 MHz.

3. A method as in claim 1 wherein the change in applied electrical current is measured as a voltage change across a resistor.

4. A method as in claim 1 wherein the representation is produced using a single electrode attached to a system for determining the electrodes position in three-dimensional space.

5. A method as in claim 1 wherein the representation is produced graphically on a screen or plot using a two-dimensional array of electrodes or rotating wheel array or cylindrical array of electrodes.

6. A method as in claim 1 wherein the representation is produced graphically by printing directly onto the skin.

7. An apparatus for measuring or imaging induced or pathological changes in skin, said apparatus including:

a measurement electrode for movement across the skin;

at least one reference electrode for application to the skin;

means for providing an alternating electrical current, coupled to the measurement electrode and/or reference electrode for supplying the current to the measurement electrode and/or reference electrode; and

means for providing a measure of the change in the alternating current indicative of the change in impedance of the skin as the measurement electrode is moved over the skin to provide an indication of the induced or pathological changes in the skin.

8. An apparatus as in claim 7 wherein the frequency of the alternating current is in the range 100 Hz to 1 MHz and the voltage in the range 1 mV to 20 volts.

9. An apparatus as in claim 7 wherein the representation is in the form of an image on a screen representing both the position and measured effect on the alternating current to provide the change of impedance.

10. An apparatus as in claim7 wherein the measuring and reference electrode is a two or three electrode design.

11. An apparatus as in claim 7 wherein the reference electrode is a subcutaneous electrode.

12. An apparatus as in claim 7 wherein a single measuring electrode is attached to a mechanism for determining its relative position in three-dimensional space.

13. An apparatus as in claim 7 wherein the measuring electrode is attached to a mechanism for printing directly onto the skin representing the relative electrical impedance change.

Figure 1.

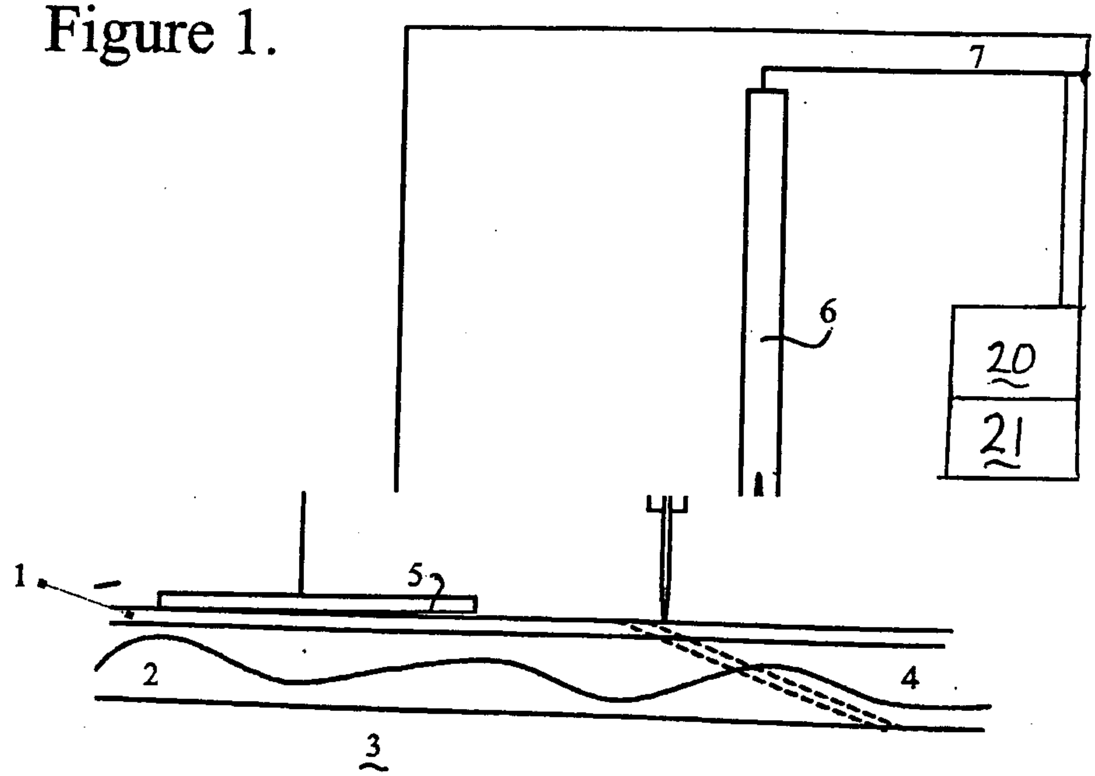
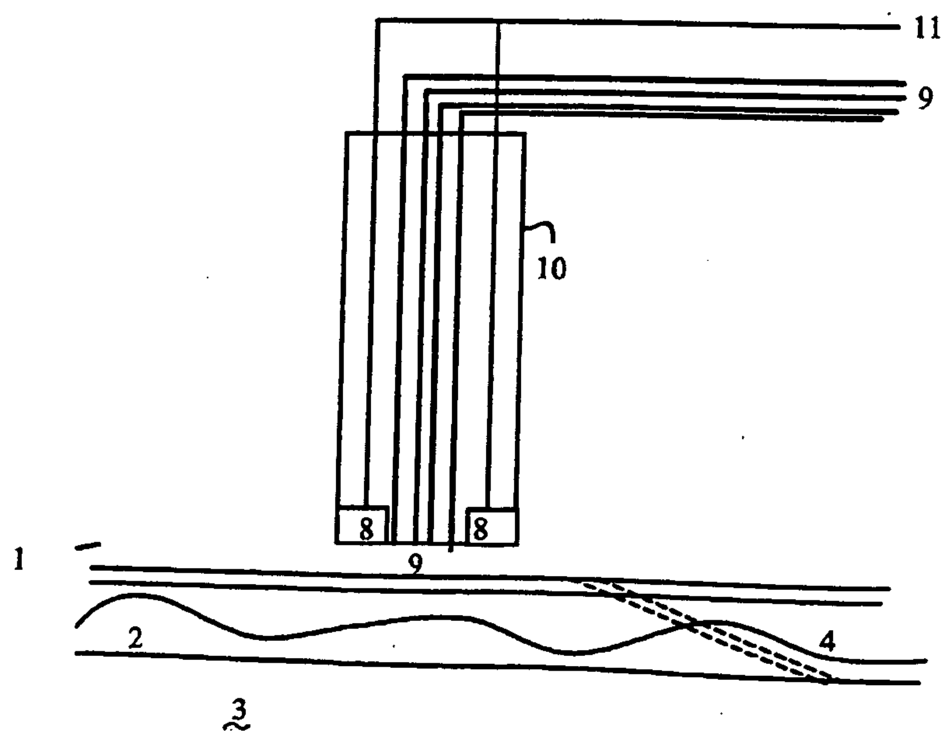


Figure 2.



INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 98/00925

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl^6: A61B 5/05, A61B 5/107

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC: A61B 5/IC

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DERWENT, JAPIO: SKIN, DERMI:, EPIDERMI:, IMPEDANCE, RESIST:, CONDUCT:, PLETHYSMOGRAPH, MEASURE, DETECT, DETERMINE, RECORD, MAP, IMAGE, PATHOLOG:, CANCER, TUMOUR, BURN, WOUND, LESION, ETC.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CONWAY, J. Electrical impedance tomography for thermal monitoring of hyperthermia treatment: an assessment using *in vitro* and *in vivo* measurements; Clin Phys Physiol Meas 1987 Vol 8 Suppl. A 141-146 Figure 5, entire document	1-3, 5-9
X Y	DT 2726630 A (DUROUX) 22 December 1977 Entire document	1-3, 7, 8, 10, 11 4, 12

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

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Date of the actual completion of the international search	Date of mailing of the international search report
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 98/00925

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP 538739 A1 (REINHARD) 28 April 1993 Entire document	1-3, 7, 8, 10, 11 4, 12
X	EP 650694 A1 (POLARTECHNICS LTD) 3 May 1995 Column 9 lines 32-33, column 10 lines 14-15	1-3, 7, 8
X Y	WO 90/09759 A1 (INFORMATSIONNO-VYCHISLITELNY TSENTROTDELA ZDRAVOOKHRANENIA PRIMORSKOGO KRAIISPOLKOMA) 24 February 1989 Abstract	1-3, 7, 8, 10, 11 4, 12
X Y	Derwent Abstract Accession No. K3774 c/43, class P31, SU 721080 A (VOROSHILOV BM) 25 March 1980 abstract	1-3, 5-11 4, 12
X Y	Derwent Abstract Accession No. 86-154602/24, class P31, SU 1191058 A (AS USSR NEUROPHYSIO) 15 November 1985 Abstract	1-3, 7, 8, 10, 11 4, 12
P, X	Derwent Abstract Accession No. 98-326130/29, class S01 S03 S05, JP 10118041 A (POLYTRONICS KK) 12 May 1998 abstract	1-3, 7, 8, 10, 11
X Y	WO 93/07809 A1 (REINHARD) 29 April 1993 abstract	1-3, 7, 8, 10, 11 4, 12
Y	US 5517990 A (KALFAS et al.) 21 May 1996 entire document	4, 12
Y	US 5383454 A (BUCHOLZ) 24 January 1995 entire document	4, 12

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU 98/00925

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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END OF ANNEX